

responsibility to notify the PTO of any litigation pertaining to this reissue application.

Presently, there is no litigation ongoing with respect to this application.

Also, the Examiner notes that the original patent or an affidavit or declaration as to the loss of or inaccessibility of the original patent must be received before reissue application can be allowed. Offers to Surrender the patent have been filed by the inventors. Upon indication of allowable subject matter, and prior to the issuance of the reissue application, the original patent or an affidavit or declaration as to its loss or inaccessibility will be supplied.

Claims 13-18 stand rejected under 35 U.S.C. §251 as being an improper recapture of broadened subject matter surrendered in the application for patent upon which the present reissue is based. Specifically, the Examiner states that during the pendency of U.S. Application Serial No. 08/289,790, which issued as U.S. Patent No. 5,665, 114, the following limitations were added to overcome a prior art rejection: "filled with a fluid which solidifies and is crosslinked to form" and "said material being insoluble at a pH of about 7.4." The Examiner concludes this is an improper attempt to recapture subject matter given up during prosecution of the prior application. This determination is respectfully traversed.

It is well settled that doctrine of recapture bars a patentee from acquiring reissue claims that are of the same or of broader scope than those claims which were cancelled from the original application. *Ball Corp. v. United States*, 221 USPQ 289 (Fed. Cir. 1984). However, it is also well settled that a patentee is free to acquire by reissue, claims that are narrower in scope than the cancelled original claims without violating the recapture doctrine. *Whitaker Corp. v.*

UNR Industries, Inc., USPQ2nd 1742 (Fed. Cir. 1990). Reissue claims which are broader in certain respects but narrower in other respects may avoid the effect of the recapture doctrine. A patentee can, therefore, obtain a reissue claim where that claim varies materially from the claim originally surrendered, even where it omits a limitation added during prosecution.

Donald S. Chisolm, Chisolm on Patents, §15.03 [2] [e] (1999).

The Examiner contends that limitation “filled with a fluid which solidifies and is crosslinked to form”, as well as the limitation “said material being insoluble at a pH of about 7.4” was specifically added during prosecution. This is not in dispute. However, the Examiner concludes that claim 13 is merely an attempt to recapture subject matter surrendered by the applicant with respect to original claim 1. It is respectfully submitted that the Examiner’s conclusion is in error.

Original claim 1, which was subsequently amended to include the aforementioned limitations, recites as follows:

An implantable member for use in repair or replacement with a body comprising an expanded polytetrafluoroethylene surface having pores present in its wall structure wherein said pores contain a solid insoluble biocompatible, biodegradable material of natural origin.

Claim 13 presented herewith recites as follows:

An implantable prosthesis comprising a body of expanded polytetrafluoroethylene having a structure of spaced apart nodes interconnected by fibrils with pores present between said nodes and said fibrils; and a biodegradable composition of natural origin contained

within said pores, said biodegradable composition forming a precipitate within said pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment.

As can be appreciated, claim 13 varies materially from the claim originally presented in the prior application. Specifically, claim 13 recites that the biodegradable composition included within the pores of the prosthesis forms a precipitate in the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. Clearly, claim 13 is narrower than claim 1 as originally presented in the parent application. Claim 13 does not attempt to recapture the subject matter originally presented in claim 1. In fact, claim 13 presents limitations which, as will be described in further detail hereinbelow, permits claim 13 to distinguish patentably over references which were cited against original claim 1. Accordingly, as claim 13 is narrower in scope than the original claims of the application, the recapture doctrine does not apply and claims 13-18 are properly submitted in the present reissue application. Reconsideration is respectfully requested.

Independent claim 1 stands rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent No. 5,197,977 to Hoffman Jr. et al (hereinafter "Hoffman"), and in view of U.S. Patent No. 5,192,310 to Herweck et al (hereinafter "Herweck"). The Examiner contends that Hoffman meets the claim limitations of a vascular graft sealed by a precipitate of collagen and solidified by crosslinking. The Examiner notes that Hoffman fails to disclose an expanded PTFE substrate, but that such a substrate is shown in Herweck. The Examiner concludes that it would have been obvious to use the Herweck PTFE graft as a substrate for the material disclosed in Hoffman. This determination is respectfully traversed.

Hoffman discloses a textile vascular graft formed of yarns which may be made from a variety of materials including Dacron and Teflon. The Hoffman graft is formed by knitting or weaving such yarns. The resulting textile product is inherently porous. In order to reduce the porosity of the textile graft, and to inhibit initial bleeding after implantation, the Hoffman graft is impregnated with collagen. Collagen impregnation of a textile graft has the stated benefit of reducing the porosity of the graft to essentially zero. This renders the graft blood tight.

Herweck discloses a vascular graft formed of an extruded tube of PTFE. The PTFE tube is subjected to secondary operations of stretching and expansion to form an ePTFE tube having a characteristic microstructure of nodes interconnected by fibrils. The microstructure of ePTFE tubes is such that there is little or no porosity exhibited by the tube. In essence, the tube as formed is blood tight. During implantation of the Herweck graft, suture holes placed through the wall of the tubular graft may allow blood leakage therethrough. In order to prevent such blood leakage, Herweck employs a self-sealing secondary lumen which consists of a non-biodegradable, elastomeric material.

Contrary to the Examiner's suggestion, one could not substitute the graft of Herweck for that shown in Hoffman. Hoffman provides a porous tube formed of textile material and provides collagen within the textile material to render the porous graft blood tight. With respect to ePTFE grafts such as that shown in Herweck, these grafts are essentially blood tight as formed. There would be no need to look toward employing collagen or any other substance to render the structure of the tube blood tight. Neither Hoffman nor Herweck, alone or in combination, suggest the provisions of an expanded PTFE substrate where the pores defined

by the nodes and fibrils of the substrate are filled with a material which is crosslinked to form a solid precipitate of an insoluble, biocompatible material of natural origin where the material is insoluble at a pH of about 7.4. As such, it is respectfully submitted that claim 1, and the claims which depend therefrom, are patentably distinct over the combination of Hoffman and Herweck. Reconsideration is respectfully requested.

Claim 1 is further rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,037,377 to Alonso in view of Herweck. The Examiner contends that Alonso discloses various porous substrates not including PTFE. The Examiner further contends that Alonso includes soluble collagen made insoluble by crosslinking. The Examiner then cites the Herweck reference in combination with Alonso for its showing of a PTFE tube. For the reasons set forth above and as further noted below, this determination is respectfully traversed.

As with the Hoffman reference above, Alonso discloses a textile vascular graft which is, as the Examiner notes, porous in nature. Specifically, Alonso discloses woven strands of polyester or other biocompatible materials. A collagen solution is applied to the graft to render the porous graft essentially blood tight. There is no disclosure at all in Alonso of the use of an ePTFE tube having microstructure of nodes and fibrils which is essentially non-porous.

Substituting the Herweck PTFE tube for the textile graft shown in Alonso is outside the contemplation of the references taken alone or in combination. Neither Alonso nor Herweck suggest providing an expanded PTFE substrate having pores defined by nodes or fibrils which is then filled with collagen to form a solid precipitate of an insoluble biocompatible material within

the pores of the ePTFE tube. As such, for the reasons set forth hereinabove, claim 1 is believed to be patentably distinct over the combination of Alonso with Herweck. Reconsideration is respectfully requested.

Claim 13 stands rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,290,271 to Jernberg. This determination is respectfully traversed.

Jernberg describes an implantable member of ePTFE which includes within the pores thereof chemotherapeutic microparticles which provide for controlled release of agents into the bloodstream. Jernberg provides for these microparticles within the matrix of the nodes of the ePTFE. The chemotherapeutic agents are encapsulated in the microparticles which may include collagen.

Claim 13 of the present invention specifically recites that the expandable prosthesis includes within its pores is a biodegradable composition forming a precipitate within the pores at selected conditions of temperature and pH so as to form an insoluble substrate site for cellular attachment. Clearly, time released therapeutic agents cannot and do not form an insoluble substrate site for cellular attachment. The purpose of the Jernberg device is to release chemotherapeutic agents which are encapsulated in microparticles. The microparticles may include collagen which allows for such time release. However, Jernberg fails to disclose in any respect forming an insoluble substrate site for cellular attachment.

It is axiomatic in patent law that, in order for a reference to be anticipatory, each and every element of the claimed invention must be disclosed in a single prior art reference. *In re Spada*, 15 USPQ 2d 1655 (Fed. Cir. 1990). As Jernberg fails to disclose a biodegradable composition within the pores which forms an insoluble substrate site for cellular attachment, Jernberg as a matter of law cannot be anticipatory of the claims of the present invention. Accordingly, it is respectfully submitted that claim 13 is patentably distinct over Jernberg.

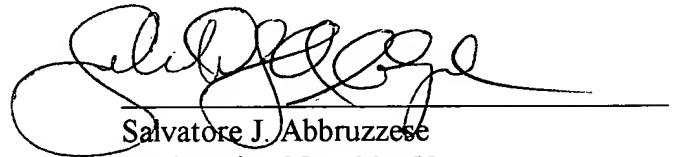
Claim 13 is further rejected under 35 U.S.C. §103(a) as being unpatentable over Hoffman in view of Herweck, and unpatentable over Alonso in view of Herweck. With respect to these rejections, the arguments presented above with respect to claim 1 are applicable.

Claim 13 recites an ePTFE prosthesis having a structure of spaced-apart nodes interconnected by fibrils with pores present between the nodes and fibrils. The biodegradable composition contained within the pores forms a precipitate therein at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. Hoffman and Alonso are both directed to textile vascular grafts, having collagen therein for making the porous graft blood tight. As set forth above, it is beyond the teachings of the cited references to combine the ePTFE substrate of Herweck with the textile grafts of Hoffman and Alonso. Even if combined, the combination still fails to disclose, teach or suggest a biodegradable composition contained within the pores of an ePTFE graft forming an insoluble substrate site for cellular attachment. It is, therefore, respectfully submitted that claim 13 is patentably distinct over the combination of Hoffman and Herweck as well as Alonso and Herweck. Reconsideration is respectfully requested.

Having responded in full to the Office Action, it is respectfully submitted that the application, including claims 1-18, is in condition for allowance. Favorable action thereon is respectfully solicited.

Should the Examiner have any questions regarding this response or wish to discuss this matter in further detail, please contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Salvatore J. Abbruzzese', written over a horizontal line.

Salvatore J. Abbruzzese
Registration No.: 30,152
Attorney for Applicant(s)

HOFFMANN & BARON
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700